

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 8932-546

Group Art Unit: 3733)
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Examiner: Richard R. Shaffer)
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Inventor: Angelucci et al.)
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Serial No.: 09/942,333)
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Filed: August 29, 2001)
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For: Laminoplasty Implants)
And Methods of Use)
)

**PRE-APPEAL BRIEF
CONFERENCE REQUEST**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby request review of the Final Rejection mailed May 4, 2006 ("Final Rejection") of the above-captioned application prior to filing an appeal brief for the reasons set forth below. Applicants submit that the Final Rejection fails to establish a *prima facie* rejection.

I. PROSECUTION SUMMARY

Independent claims 1 and 18 were rejected in a Non-Final Office Action mailed January 24, 2006 ("Non-Final Office Action") under 35 U.S.C. § 103(a) unpatentable over Hirabayashi et al., "Contact of hydroxyapatite spacers with split spinous processes in double-door laminoplasty for cervical myelopathy," J. ORTHOP. SCI., 4:264-268 (1999) ("Hirabayashi") in view of U.S. Patent No. 6,511,509 to Ford et al. ("Ford"). In response, Applicants argued that neither Hirabayashi nor Ford taught, suggested or disclosed an implant having first and second bone engaging portions and an inner side region, "wherein the inner side region is angled with respect to each of the bone engaging portions at an angle ranging from about 50 to about 70 degrees."

Examiner thereafter affirmed the rejections of claims 1 and 18 in the Final Rejection. Specifically, Examiner stated that Hirabayashi disclosed "an angle ranging from about 50 degrees to about 70 degrees" from its photographs. (Final Rejection at 4). Examiner further stated that although Hirabayashi failed to disclose an implant having "a substantially hollow portion," it would have been obvious to modify the Hirabayashi implant in light of Ford. (*Id.* at 2-3).

II. FAILURE TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS

A *prima facie* case of anticipation or obviousness has not been made with regard to independent claims 1 and 18 because the cited art fails to disclose, teach, or suggest each and every element of claims 1 and 18.

Independent claims 1 and 18 recite an implant insertable between first and second bone ends or segments, having first and second bone engaging portions and an inner side region, "wherein the inner side region is angled with respect to each of the bone engaging portions at an angle ranging from about 50 to about 70 degrees." Examiner has repeated stated that Hirabayashi "discloses the development and optimization of implants for double-door laminoplasty, wherein the resulting implants have angled surfaces clearly within the

claimed range of “about 50 to about 70 degrees.”” (Non-Final Office Action at 3; Final Rejection at 2).

Hirabayashi describes experiments held using the STSS spacer in laminoplasty applications “to evaluate the contact rate of the STSS spacer with spinous process in patients.” (*Id.* at 264). However, although the STSS spacer is shown to be generally trapezoidal in shape (*see* Fig. 1b), Hirabayashi discloses no angles for the STSS implant described therein. Moreover, the purpose of the Hirabayashi study was to determine the *contact* of a specific implant (the STSS) with the spinous process — Hirabayashi does not explicitly or implicitly implicate the *angles* of the STSS implant as having anything to do with achieving this goal. Rather, Hirabayashi states that implant *shape and size* are relevant considerations in achieving sufficient contact between the implant and spinous process, which are only configurable *after* the spinous process is bisected. (*Id.* at 267-68). Thus, not only is there is no disclosure of angles in Hirabayashi, there is no suggestion or motivation to arrive at angles “ranging from about 50 to about 70 degrees” to optimize the STSS implant. *See In re Antonie*, 559 F.2d 618 (CCPA 1977) (not obvious to modify to optimize when reference did not recognize the result-effective variable).¹

Independent claims 1 and 18 further recite an implant having “an inner surface defining a substantially hollow portion,... and first and second ends which communicate with said hollow portion.” Examiner has admitted that Hirabayashi does not specifically disclose an implant “having a substantially hollow portion,” but asserts that “it would have been obvious... to combine the basic inventive concept of Hirabayashi with the teachings of Ford to produce the applicants [*sic*] claimed invention.” (Final Rejection at 2-3).

As stated above, the purpose of the study in Hirabayashi was to determine the *contact* of a specific implant (the STSS) with the spinous process, and more particularly, *to maximize*

¹ Indeed, Examiner points to nothing to support the statement that “Hirabayashi could be modified to include these angles... since discovering an optimum range or workable range only involves routine skill in the art.” (Final Rejection at 4).

the contact area by varying the shape and size of the STSS spacer. A score of “excellent” resulted from “complete touch on both sides of the spacer to the spinous process.” (*Id.* at 264). Moreover, “the appropriate size of the spacer must be selected in accordance with the size of the spinous process to obtain higher percentages of excellent or good contact.” (*Id.*). To achieve greater contact, STSS implants were used that had solid, continuous surfaces, and accordingly “contact between the spacer and the spinous process was assessed by measuring the extent of touch of the spacers to the spinous process.” (*Id.* at 265).

Thus, there would be no motivation to modify the Hirabayashi STSS spacer to have “an inner surface defining a substantially hollow portion,... and first and second ends which communicate with said hollow portion,” as doing so would *reduce* the available surface area to create contact between the implant and the spinous process. In fact, such a modification is directly contrary to the teachings of Hirabayashi, which instead expressly teaches to *maximize* the contact area. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (as a “general rule,” a reference that teaches away cannot serve to create a *prima facie* case of obviousness). Thus, Hirabayashi cannot be used as the basis of an obviousness rejection of claim 1 or 18.

Ford fails to remedy the deficiencies of Hirabayashi. Although Ford does show implants having hollow portions extending between two ends (*see, e.g.*, Figures 1A-1B), there still exists no motivation to combine Hirabayashi with Ford to arrive at the claimed implants. It is not sufficient merely say motivation comes from knowledge of those having skill in the art — indeed, “[a] statement that modifications of the prior art to meet the claimed limitation would have been ‘well within the ordinary skill of the art at the time the claimed invention was made’ because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.” MPEP § 2143.01 (citing *Ex parte Levengood*, 28 U.S.P.Q. 2d 1300 (Bd. Pat. App. & Inter. 1993) (emphasis in original)).

Applicants accordingly submit that Examiner has not made out a *prima facie* case of obviousness of independent claims 1 and 18. Applicants therefore submit that independent claims 1 and 18, in addition to dependent claims 3-17, 20-24, and 26, are allowable.

III. CONCLUSION

For at least the above reasons, Applicants submit that claims 1, 3-18, 20-24, and 26 are in condition for allowance.

Respectfully submitted,

Date: April 11, 2007

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